

Quality/Food Safety Manual

Document Title: 22-26_FSQM_Food Fraud and Defense Plan

Owner: Food Safety - Deborah Aber

Effective Date: 07/26/2021



1.0 Purpose

To identify and assess any hazards to products posed by security of the site and personnel

2.0 Scope

All Vigon Employees and Facilities

3.0 General Information

ISO 22000:2018	ISO 22000:2005 TS 22002
4. Context of the Organization	18.1 Food Defense, Biovigilance, and Bioterrorism
8.2 PRP	18.2 Access Controls
9.1 Monitoring, Measurement, Analysis, and Evaluation	5.5 Lab Facilities

4.0 Responsibility

Food Safety Team Leader- Ensure that the food defense program is up to date on current CTPAT and FDA laws in according to site security

Facilities Manager- Manages Security Contracts, Maintenance of the Security System, ID and Access Control

All Employees- Monitor and Communicate any suspicious activity to your supervisor

5.0 Details

5.1 Vulnerability Assessment

Vigon has completed a vulnerability assessment to locate potentially sensitive areas for security breaches and intentional malicious contamination. This is located in the Food Defense Plan as specified by the FDA [Food Defense Plan Builder](#)

5.2 Mitigation Strategies

1. Facility Security

A. Property

Vigon International is comprised of five buildings. Four are located on a 17 acre campus in Smithfield Township and the other used as overflow storage located on a 5 acre site in the town of East Stroudsburg.

- i. The Manufacturing Building is an approximate 35,000 sq ft building which facilitates operations, laboratory testing, raw material storage, maintenance, and flammable storage.
- ii. The Distribution Building is approximately 30,000 sq ft and facilitates distribution, down-packing, and sampling of incoming raw materials.
- iii. The Quonset-Hut is used for maintenance and administration storage.
- iv. The Administration Building contains offices for customer service, HR, Sales, Accounting, and IT
- v. Overflow Warehouse Storage Facility (Crowe Rd) is used for overflow storage of our distribution materials.

B. Vehicle Access and Parking Lot

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The Manufacturing, Distribution, and Overflow Buildings are limited to one entrance and exit. Each of these is controlled by a vehicle gate which remains unlocked during business hours. During non-business hours or no employee presence, the vehicle gates are locked, restricting vehicular traffic.

All Buildings have means to light parking lots for employees or visitors. These can be through flood lights or Motion sensor lighting.

2. Building Security

A. External Access Controls

All entrances are locked at all times and only accessible through an electronic scan card or pin with visitors only being granted access by an employee at Vigon International. The four main access points for visitors are

- i. Administration Office by the main receptionist
- ii. MFG Production Office by the Maintenance receptionist
- iii. Production Trucker Entrance by Shipping and Receiving Specialist
- iv. DC Trucker Entrance by DC Shipping and Receiving Specialist

Each Visitor will log into the electronic IPAD terminal to designate who they are seeing (escort) which will send an e-mail to the appropriate person. This person now becomes the visitors escort until the visitor checks out. Visitors will be issued a paper badge with their name and who they are visiting. For contractors who are approved for long term visits to the facility an electronic scan card can be given for access to the building which will be logged by Maintenance Receptionist.

Each Building is monitored by a 3rd party electronic security contractor. This company installs sensors on windows, motion detectors, and a security alarm which requires a 4 digit pin pass code to disarm or alarm buildings during non-shift hours. This company contacts the local police or fire depts. and activates a Vigon call list in the event of any triggered security alarms.

The company also logs the frequency and pin codes used for disarming or alarming the buildings to log any suspicious activity that could be internal.

For any external doors that have a physical pin code to unlock the door. These are changed yearly and are being placed out of service as Vigon continues to grow and update our security programs.

B. Internal Access Controls

An additional layer of security has been implemented to protect the manufacturing, distribution, Crowe Road, and laboratory facilities of the company to minimize foot traffic and security risks to sensitive parts of our facilities for contractors, visitors, and employees. Each facility can only be accessed through an employee badge that has special permissions to the given area based on job description.

All non-food grade chemicals are stored in separate, locked, and restricted areas

3. Security Assessments

An annual Security Assessment is conducted utilizing the following checklists:

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- 1) Facility Security Checklist (SEC101F1)
- 2) Receiver Security Checklist (SEC101F2)
- 3) Shipper Security Checklist (SEC101F3)

Any actions required will be recommended through the use of this checklist upon completion of the assessment and will be submitted for a work order

a. Personnel Security

Pre-Employment Security

All candidates for employment are required to submit an application for employment which includes a complete history of prior employment and personal references. These are verified as is determined necessary through a thorough interview process which includes a minimum of two interviews with at least two current Vigon employees.

In addition, a background check is completed prior to an individual's offering for employment. This background check includes Social Security verification, drug screening, and federal/state criminal background check. The results of all background checks are retained in the permanent employee file. A third party may be contracted to conduct any or all items listed. Any suspicious information will be reported to the President.

Active Employee Security

Employees complete the Employment Eligibility Verification I-9 Form upon date of hire which is used for employment eligibility. Background checks are not currently conducted on any active employees, regardless of position. Those who were hired prior to September 25th, 2003 did not have an initial background check. Background checks on active employees are done only if circumstances warrant one.

Employee Security Training

All employees are required to complete security training within the first 90-days of employment. This training program relates directly to the storage and transportation of hazardous materials. The training program meets the requirements of current DOT regulations 49 CFR 172.800-804 regarding the training of employees engaged in the preparation of hazardous materials for transport. It provides employees with an introduction to the potential threat associated to the transportation and storage of hazardous materials, specifically as it relates to potential threats of terrorism. It also provides employees with basic information regarding how to identify potential threats in the workplace. FDA Food Defense (First) training is completed by employees on HSI platform.

Employees who have specific responsibilities relating to security as well as those who are provided with keys to the building(s) for access are trained on related policies and procedures.

b. Information Technology Security

In order to gain access to the network, all employees are required to utilize a unique username and password combination which gives employees access based on responsibilities. Email is hosted offsite and can be accessed either through network access or directly going to our mail website and logging in with a unique username and password. Within the network, the primary financial, inventory, and sales program requires an additional unique username and password for access Email is accessible to all employees.

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The company website is hosted offsite and therefore provides little security threat to our network. On the premises, there are wireless networks established to support RF scanning capability within the warehouse. There are also guest networks, which require a password, that these wireless networks support, but the guest network has no access to the company network. These wireless networks are encrypted to prevent any unauthorized external access.

In addition to the access limitations already identified, the network includes a perimeter firewall. Vigon uses Sonicwall devices which provide extensive protection against the infiltration of malicious access. External access to the network is limited to those who have a unique user name and password and access is gained through a secure VPN client. There is additional access to our network externally using TeamViewer. TeamViewer uses encryption based on 2048bit RSA private/public key exchange and 256 bit AES session encoding.

Employees who are provided with Smart phones and laptops which include access to company email must password protect their phones, laptops and any other portable device which can access Vigon email.

c. Shipping and Receiving Security

Inbound Conveyance Security

When shipments are received via sealed container, the container seals are verified to be intact prior to the conveyance being docked for unloading. In addition, a physical inspection of the exterior is done to identify any potential areas of infiltration. If seals are not intact or if there is any evidence of risk of infiltration, a decision is made by senior management to either refuse the shipment or proceed with unloading the container and receiving the material using a stringent procedure to minimize security risk.

Inbound Material Security

All inbound material is verified against the driver manifest (bill of lading or packaging list) before being accepted. This includes verification of the number of containers received, the packaging materials described, and the condition of the containers. If any container shows signs of tampering or potential infiltration, it is refused or securely segregated and is subject to additional testing to ensure product is intact as shipped. Both the shipper and the carrier would be notified of the issue to ensure awareness throughout the supply chain.

Tamper proof seals are required on all inbound containers and/or packages. We require our suppliers to use identifiable seals to minimize the opportunity for unidentified tampering. Any container which does not contain such a seal will be subject to thorough testing to ensure that no tampering has occurred.

Vendors will be notified of any such occurrences and if any evidence of tampering is uncovered, appropriate law enforcement officials would also be notified.

Vigon has partnered with approved 3rd party contracted company who picks up all Vigon containers at the port and inspects them at their facility prior to opening, opens and strips the container and then delivers the material to Vigon. In most instances, Vigon does not inspect each container but relies on an approved 3rd party contracted company to do so. Vigon has an agreement with an approved 3rd party contracted company regarding the inspection of all containers and Vigon freight and what actions to take in the event of an incident.

The receiving process is designed to ensure that all product received matches exactly against the documents provided by the shipper. According to a written procedure, a certain proportion of all containers received are

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weighed to ensure accuracy of weights shipped. In addition, a certain proportion of containers are sampled to ensure product quality, including any evidence of infiltration.

All shortages and overages are reported to the supplier for verification. This includes rechecks of their inventory to determine the source of the error. Employees are aware of the security risks that could be associated with overages and shortages. If any evidence suggested that an overage or shortage was the result of unauthorized tampering or other security violation, law enforcement would be notified.

4. Food Defense Monitoring, Corrective Action, and Verification

- a. Monitoring of internal and external food threats occurs by testing raw materials and finished products in the laboratory on specialized equipment to determine if they meet Vigon specifications. New items with large monetary values will undergo C-14, SNIF-NMR, IR, or GC testing.
- b. A 3rd party electronic security contractor tests the system daily to ensure the system is operating correctly.
- c. Vigon completes annual security audits and monthly verifications that doors are operating correctly.
- d. Corrective actions regarding the security system will be documented in the emaint system
- e. If a malicious or fraudulent event occur, the product will be placed in immediate quarantine or tagged as hazardous waste, and state or federal authorities will be called to investigate. A food safety exception form will be completed.

5. Food Fraud

Vulnerability Assessment and Analysis of Potential Food Fraud Products

Food Fraud is defined as fraudulent and intentional substitution, dilution, mislabeling, counterfeiting, or addition to a raw material or food product, or misrepresentation of the material or product for financial gain by increasing its apparent value or reducing its cost of production.

There are 2 recognized means of identifying and preventing Food Fraud. First is to control your supply chain and the products that come into the facility. This will be referred to as controlling Industry Food Fraud. The second way is to control our own facility and internal work practices to ensure we don't inadvertently incentivize behaviors that could result in a Food Fraud situation. This will be referred to as controlling Internal Food Fraud.

Industry Related Food Fraud

One commonly recognized method to detect and/or prevent Industry Related Food Fraud is to research/monitor trends and/or past cases of Food Fraud within the industry. This typically involves high value ingredients that are prone to shortages. Therefore, vulnerable flavors will typically make claims such as "natural" or from a specific region (i.e. Madagascar Vanilla). For the Food and Flavors industry, ingredients commonly targeted for Food Fraud are Essential Oils, Vanillin Natural, Natural Ketones, and Benzaldehyde.

Known Methods for Fraud –

1. Mislabeling of Natural for Synthetic Vanillin
2. Diluting of Concentrated Liquid Flavor Products with Alcohol, Water, Fixed Oils, or Synthetic isolates.
3. Diluting of Pure liquid product with less expensive similar flavor ingredients. (Lemon Terpenes in Lemon Oil, adding Lavandin Oil to Lavender Oil, etc.)
4. Diluting of Powder products with carriers (i.e. Maltodextrin)

Industry Control Measures for Claim Testing-

1. C-14 Testing –Carbon Dating to distinguish Natural vs Artificial Raw Materials

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2. Sniff NMR – Origin-Botanical, Synthetic/Natural, Geographical Area of Product
3. GC and GC MS to identify when specific peaks (markers) are out of the normally expected tolerances.

Vigons Mitigation Measures for Industry Food Fraud:

- A. New Supplier Controls – New Suppliers that are not well known in the industry are reviewed as a legitimate company before approval. Any fraudulent or criminal charges will be assessed during the financial supplier onboarding. Foreign suppliers are also risk assessed and import alerts are monitored (please see Foreign Supplier Verification Document 06-01-01)
- b. New Item Controls – Items deemed as high value with claims will be tested for C-14, SNIF-NMR, IR, and/or GC MS testing.
- c. Item questionnaires are reviewed by food safety to determine the fraud risk to the product.
- d. GC Sampling of every Lot – Pre-Shipment samples are fully tested before item or supplier is setup in ERP. Approved items will be lot tested by GC at the facility and compared to the approved pre-ship sample to close the quality loop.
- e. Risk assessments- Vigon will complete risk assessments for categories of raw materials and run the items through Decernis software. Vigon may also utilize Trello, RASFF, and the Food Adulteration Incidents Registry to gather information for food fraud risk assessments. The Food Fraud Risk Assessments and Mitigation Strategies can be found in OneDrive:/Foodsafety/Food Fraud. If the risk assessment indicates a high risk ingredient it will be entered into VACCP and a mitigation strategy will be developed for the ingredient. The mitigation may be controlled through Vigon, or Vigon may ask their supplier to control the risk to the ingredient with specific testing.

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Ingredient Vulnerability Assessment – VACCP

Questions with "*" "yes" answers will be V-CCP and require additional supporting documents from supplier to confirm – "No Fraud"
 L = Likelihood: 1 2 3 4 5 (low to high) C = Economic Consequence: 1 2 3 4 5 (low to high)

Ingredient	Supplier	Assessment							Likelihood	Economic Consequence	Risk = L+C	Is the potential food fraud reasonably Likely to occur? Yes R ≤ 8 No R > 7	V-CCP yes/no	CCP
		Approved Supplier yes/no	*Supplier –History of fraud (yes/no)	Internet Search for fraud (yes/no)	*Food Fraud findings from internet search (yes/no)	Mitigation Strategy? (yes/no)								
Biochemicals \$1000-\$5000	[Redacted]	Yes	no	yes	No	no			1	2	3	no	no	
Biochemicals \$5000 - \$100,000	[Redacted]	Yes	No	Yes	No	No			4	3	7	yes	yes	Supplier approval program, quality testing,
Tea Products	[Redacted]	Yes	No	Yes	Yes	No			3	2	5	No	no	
Honey	[Redacted]	Yes	No	Yes	Yes	No			1	1	2	No	No	
Vanilla	[Redacted]	yes	No	Yes	Yes	yes			1	2	3	No	Yes	GC testing on arrival
Fruit Juice Concentrates	[Redacted]	Yes	No	Yes	Yes	No			3	2	5	No	No	
Mustard Oil	[Redacted]	Yes	No	Yes	Yes	Yes			4	3	7	Yes	yes	Phenol test

Nut and spice oils	[Redacted]	yes	No	yes	No	No			2	1	3	No	No	
Vanillin Natural	[Redacted]	Yes	No	Yes	Yes	Yes			3	2	5	NO	No	We do GC testing on every incoming shipment to ensure it is natural vanillin

Internal Related Food Fraud

Internal Food Fraud relates to company employees or processes directly increasing apparent product value or decreasing production cost. The list below identifies products over \$1000 dollars per kilogram. The vulnerability of these items increase they as are handled and/or produced on the production floor. Highlighted

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yellow items are used in small quantities to make flavor profiles while the highlighted red items are produced or reconditioned in large quantities. The highest risk and most vulnerable items are marked in red.

500422	IRONE ALPHA -Prod
504388	VANILLA BOURBON SFE ORGANIC
501373	VANIPROX BASE NATURAL
501299	PHENYLACETIC ACID NATURAL
501331	ETHYL-5 3-HYDROXY 4-METHYL 2(5H)-FURANONE - Prod
500477	MASSOIA LACTONE-Prod
502760	DAMASCENONE-Prod
501361	METHYL CORYLONE - Prod
501335	LEMON OIL TERPENELESS WONE
503974	JASMINE ABSOLUTE INDIA 100% PURE

Table 1: Top YTD Sales for Items that are over \$1000/kg

Increasing Product Value: Increasing product value entails making claims regarding a product (100% Natural, from a specific origin, etc.) This concern is vetted through our supplier and item approval process and not deemed vulnerable with our current internal processes.

Decreasing Production Cost: Decreasing production cost for overall net company profit would be obtained through diluting raw materials, addition of a lower cost similar flavors, or addition of a filler/extender. The most common cause of internal food fraud is offering incentives of some sort to increase yields of manufactured goods. Currently, our Yearly Management Review Meeting is designed to discuss and flush out these issues when they occur. The second most common reason for internal food fraud is via direct economic gain by an employee stealing product and replacing with some cheaper variant or extender. The items highlighted are at higher risk because employees are directly working with the products. Lab testing protocols, Employee training, and Security programs are used to mitigate this risk.

Vigon International's Mitigation Measures for Internal Food Fraud:

Security Program: RFID Scan Cards for approved employees in vulnerable areas as well as an expansive 100+ CCTV Security Cameras. Multiple employees working in areas will also reduce the risk of internal food fraud. Container sizes will deter an employee from stealing high value product as the container sizes are too big to hide.

Lab Testing: Every lot of raw material and finished product is tested for purity and possible adulteration

Yearly Management Meeting: High Level goals are discussed yearly for business units. The goals are further discussed to make sure there are no conflict of interests.

Risk assessments are completed for high risk ingredients

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If a malicious or fraudulent event occur, the product will be placed in immediate quarantine or tagged as hazardous waste, and state or federal authorities will be called to investigate. A food safety exception form will be completed.

6. Reanalysis

1. Food defense plan will be re-analyzed every year or when significant changes are made to the system that creates a new or potential vulnerability. Re-analysis of food defense plan will also occur if mitigation strategies are ineffective or not properly implemented, or if FDA or other agency identifies new threats to the system.

7. Related Documents

Facility Security Checklist (SEC101F1)
Receiver Security Checklist (SEC101F2)
Shipper Security Checklist (SEC101F3)
Food Defense Plan Builder
06-01-01 Foreign Supplier Verification Program

8. Related Records

Annual Security Assessment Records (Facility Security Checklist (SEC101F1), Receiver Security Checklist (SEC101F2), and Shipper Security Checklist (SEC101F3))

9. Related References

49CFR 172.704 Training Requirements
49CFR 172.800 Purpose and applicability
49CFR 172.802 Components of a security plan
49CFR 172.804 Relationship to other Federal requirements
21 CFR 121. Food Defense Measures
Decernis food fraud software